



PATENT APPLICATION
Atty. Dkt. No.: 2206-001C

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Morton M. MOWER

Appln. No.: 10/053,750

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Examiner: Jastrzab, J.

For: AUGMENTATION OF ELECTRICAL CONDUCTION
AND CONTRACTILITY BY BIPHASIC CARDIAC
PACING ADMINISTERED VIA THE BLOOD POOL

REQUEST FOR INTERFERENCE UNDER 37 C.F.R. § 41.202

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

A. Claims 10-15, 17-20, 22, 24-25, 34-36, 38, 47, 50, and 58-66 are currently pending in the application. Claims 10-11 and 58-66 are withdrawn from consideration as being non-elected. Applicant respectfully requests declaration of an interference in accordance with 37 C.F.R. § 41.202. The reasons for granting this request follow.

B. Identification of Patents

In accordance with 37 C.F.R. § 41.202(a)(1), Applicant identifies U.S. Patent No. 6,236,887 (hereinafter the '887 Patent), U.S. Patent No. 6,233,484 (hereinafter the '484 Patent), U.S. Patent No. 6,463,324 (hereinafter the '324 Patent), U.S. Patent No. 6,330,476 (hereinafter the '476 Patent), and U.S. Patent No. 6,317,631 (hereinafter the '631 Patent). The '887 and '324 Patents relate to non-elected, withdrawn claims.

C. Proposed Count 1 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 1 directed to an apparatus for treatment of cardiac muscle:

May 26, 2006

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COUNT 1

Apparatus comprising
circuitry for creating a non-excitatory electric potential between at least two points
located in the vicinity of the muscle, and
comprising circuitry for controlling the start time and/or duration of the electric
current flowing between said at least two points which is synchronized to heart
activity, said circuitry not operating at every beat of the heart.

C.1. Correspondence of Patent Claims to Proposed Count 1

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 1, 4, and 46-50 of the '484 Patent correspond to proposed Count 1. This correspondence is explained as follows.

Independent claims 1, 4, and 46-50 of the '484 Patent correspond to proposed Count 1, although they are not exact duplicates thereof.

One difference between independent claim 1 and proposed Count 1 is that claim 1 recites that the "circuitry for controlling the start time and/or the duration of the electric potential" is a part of the "circuitry for creating a non-excitatory electric potential," whereas proposed Count 1 recites these as two separate structures. There is little meaningful difference between these two descriptions of the invention since the same limitations are recited in each, albeit organized slightly differently. This is not a difference of patentable distinction.

Another difference between independent claim 1 and proposed Count 1 is that claim 1 recites "controlling the start time and/or the duration of the electric potential generated between" two points, whereas proposed Count 2 recites "controlling the start time and/or duration of the electric current flowing between" two points (emphasis added to show contrasting language). As a matter of physics, the start time and duration aspects of the current and the electrical potential in this context are synonymous. In the biomedical context in which this invention operates, there would not be anything to cause current and potential to be shifted or stretched with respect to one another in any meaningful way.

The only difference between independent claim 4 and proposed Count 1 is that claim 4 recites in its preamble that the apparatus is "for selectively and reversibly reducing the oxygen

consumption of an area of a muscle,” whereas proposed Count 1 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose of reducing oxygen consumption is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breathe life and meaning into the purpose recitation in the preamble.

The only difference between independent claim 46 and proposed Count 1 is that claim 46 recites in its preamble that the apparatus is “for performing heart surgery,” whereas proposed Count 2 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose of surgery is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breathe life and meaning into the purpose recitation in the preamble.

One difference between independent claims 47-50 and proposed Count 1 is that the “circuitry for controlling the start time and/or the duration of the electric potential” is a part of the “circuitry for creating a non-excitatory electric potential,” whereas proposed Count 2 recites these as two separate structures. There is little meaningful difference between these two descriptions of the invention since the same limitations are recited in each, albeit organized slightly differently. This is not a difference of patentable distinction.

Another difference between independent claim 47 and proposed Count 1 is that claim 47 recites in its preamble that the apparatus is “for promoting the healing of the hibernated area of the cardiac muscle after myocardial infarct,” whereas proposed Count 1 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose of promoting healing is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breathe life and meaning into the purpose recitation in the preamble.

Another difference between independent claim 48 and proposed Count 1 is that claim 48 recites in its preamble that the apparatus is “for promoting the healing of an ischemic area of the cardiac muscle,” whereas proposed Count 1 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose of promoting healing is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breathe life and meaning into the

purpose recitation in the preamble.

Another difference between independent claim 49 and proposed Count 1 is that claim 49 recites in its preamble that the apparatus is “for treating congenital or acquired hypertrophic cardiomyopathy,” whereas proposed Count 1 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose of treating hypertrophic cardiomyopathy is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breath life and meaning into the purpose recitation in the preamble.

Another difference between independent claim 50 and proposed Count 1 is that claim 50 recites in its preamble that the apparatus is “for aiding in performing cardiac ablation,” whereas proposed Count 2 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose of aiding cardiac ablation is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breath life and meaning into the purpose recitation in the preamble.

Dependent claim 52 of the ‘484 Patent also corresponds to proposed Count 1. This dependent claim describes in greater detail various aspects of the same invention to which proposed Count 1 is directed.

The correspondence of independent claim 1 of the ‘484 Patent to proposed Count 1 is set out in tabular form in Attachment A.

C.2. Correspondence of Application Claims to Proposed Count 1

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 12 and 14 of this application correspond to proposed Count 1. This correspondence is explained as follows.

Independent claims 12 and 14 of the present application correspond to proposed Count 1, although they are not exact duplicates thereof.

One difference between independent claim 12 and proposed Count 1 is that claim 12 recites that the “circuitry for controlling the start time and/or the duration of the electric potential” is a part of the “circuitry for creating a non-excitatory electric potential,” whereas proposed Count 1 recites these as two separate structures. There is little meaningful difference between these two descriptions of the invention since the same limitations are recited in each,

albeit organized slightly differently. This is not a difference of patentable distinction.

Another difference between independent claim 12 and proposed Count 1 is that claim 12 recites “controlling the start time and/or the duration of the electric potential generated between” two points, whereas proposed Count 1 recites “controlling the start time and/or duration of the electric current flowing between” two points (emphasis added to show contrasting language). As a matter of physics, the start time and duration aspects of the current and the electrical potential in this context are synonymous. In the biomedical context in which this invention operates, there would not be anything to cause current and potential to be shifted or stretched with respect to one another in any meaningful way.

A final difference between claim 12 and proposed Count 1 is that instead of including a limitation of “said circuitry not operating at every beat of the heart,” claim 12 includes the limitation of “said non-excitatory electric potential being a first phase of a biphasic pacing pulse.” However, Applicant submits that “demand pacing,” in which pacing is done only as demanded or needed instead of at every beat of the heart (and thus “not at every beat of the heart”) was well known in the pacemaker art as of 1996 and that it would have been obvious to modify Applicant’s invention to apply Applicant’s pacing invention to demand pacing pacemakers. As such, it renders the subject matter obvious, as required by 37 C.F.R. 41.203.

A difference between independent claim 14 and proposed Count 1 is that claim 14 recites in its preamble that the apparatus is “for varying conduction velocity of a muscle,” whereas proposed Count 1 is silent as to what the apparatus is to be used for. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim. It is noted that the recited purpose is not mentioned in the body of the claim and, thus, the material limitations of the claim do not breath life and meaning into the purpose recitation in the preamble.

A final difference between claim 14 and proposed Count 1 is that instead of including a limitation of “said circuitry not operating at every beat of the heart,” claim 14 includes the limitation of “said non-excitatory electric potential being a first phase of a biphasic pacing pulse.” However, Applicant submits that “demand pacing,” in which pacing is done only as demanded or needed instead of at every beat of the heart (and thus “not at every beat of the heart”) was well known in the pacemaker art as of 1996 and that it would have been obvious to modify Applicant’s invention to apply Applicant’s pacing invention to demand pacing

pacemakers. As such, it renders the subject matter obvious, as required by 37 C.F.R. 41.203.

C3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

C4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant's claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

D. Proposed Count 2 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 2 directed to causing non-excitatory electric current to flow between points located in the vicinity of the heart, drafted in the "or" format:

COUNT 2

Implantable apparatus comprising
circuitry for causing a non-excitatory electric current to flow between at least two
points located in the vicinity of a muscle and
circuitry for controlling the start time and/or duration of the electric current, wherein
said circuitry for controlling does not operate at every beat of the heart.

D.1. Correspondence of Patent Claims to Proposed Count 2

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 2, 13, 30, and 38 of the '484 Patent correspond to proposed Count 2. This correspondence is explained as follows.

Independent claim 2 of the '484 Patent corresponds exactly to proposed Count 2. The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.203(a).

D.2. Correspondence of Application Claims to Proposed Count 2

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 13 of this application correspond to proposed Count 2. This correspondence is explained as follows.

Independent claim 13 of the present application corresponds closely to proposed Count 2, although it is not an exact duplicate thereof. The difference between claim 13 and proposed Count 2 is that instead of including a limitation of “said circuitry for controlling does not operate at every beat of the heart,” claim 13 includes the limitation of “said non-excitatory electric current is a first phase of a biphasic pacing pulse.” However, Applicant submits that “demand pacing,” in which pacing is done only as demanded or needed instead of at every beat of the heart (and thus “not at every beat of the heart”) was well known in the pacemaker art as of 1996 and that it would have been obvious to modify Applicant’s invention to apply Applicant’s pacing invention to demand pacing pacemakers. As such, it renders the subject matter obvious, as required by 37 C.F.R. 41.203.

D.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

D.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant’s claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

E. Proposed Count 3 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 3 directed to an apparatus for creating a non-excitatory electric potential between points located in the vicinity of a muscle:

COUNT 3

Apparatus, comprising:

means for creating an electric potential between at least two points located in the vicinity of the muscle;

means for causing a non-excitatory DC electric current to flow between said at least two point, if desired; and

means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two points.

E.1. Correspondence of Patent Claims to Proposed Count 3

E.1.a The '484 Patent and Proposed Count 3

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 5 of the '484 Patent correspond to proposed Count 3. This correspondence is explained as follows.

Independent claim 5 of the '484 Patent corresponds exactly to proposed Count 3 with the exception of the intended use phrase in the preamble of "for reducing the contraction force of a muscle" which is not given patentable weight since it is not referred to in the body of the claim.

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.203(a).

E.1.b The '631 Patent and Proposed Count 3

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 53 and 54 of the '631 Patent correspond to proposed Count 3. This correspondence is explained as follows.

Independent claims 53 and 54 of the '631 Patent correspond to proposed Count 3, although they are not exact duplicates thereof.

One difference between the proposed Count 3 and the claims of the '631 Patent is that claim 53 describes a "cardiac surgery aiding" apparatus and claim 54 describes a "cardio-vascular surgery aiding" apparatus. This is merely a recitation of an intended use of the apparatus and does not materially limit the claim.

Another difference between the proposed Count 3 and the claims of the '631 Patent is that the Count recites

means for creating an electric potential between at least two points
located in the vicinity of the muscle;

whereas claims 53 and 54 of the '631 Patent recite

circuitry for generating a non-excitatory electric field.

These two phrases have the same meaning and are simply expressing a description of the

same structure in a different form of words.

Another difference between the proposed Count 3 and the claims of the '631 Patent is that the Count recites

means for causing a non-excitatory DC electric current to flow
between said at least two point, if desired

whereas claims 53 and 54 of the '631 Patent recite

electrodes for applying to a heart or to a portion thereof said non-
excitatory electric field.

These two phrases have the same meaning and are simply expressing a description of the same structure in a different form of words. The former is phrased in the form of limitation under § 112, ¶ 6th that embraces a range of functional equivalents, whereas the latter is phrased by articulating a structure that embraces the same function.

Another difference between the proposed Count 3 and the claim 53 of the '631 Patent is that the Count recites

means for controlling the start time, duration and magnitude of the
non-excitatory electric potential and/or of the non-excitatory electric
current flowing between said at least two points

whereas claim 53 of the '631 Patent recites

wherein said circuitry for generating a non-excitatory electric field
generate a field of a magnitude, shape duty cycle, phase, frequency and
duration suitable to control the electro-mechanical activity of the tissue in
the area on which surgery is to be performed, and wherein said field is
unable to generate a propagating action potential.

The results of "said field is unable to generate a propagating action potential" and "non-excitatory electric potential" have the same meaning and are simply expressed in a different form of words. The sets of parameters controlled in each case are so thoroughly overlapping as to patentably indistinct from one another. The wording as to "the area on which surgery is to be performed" is simply a statement of intended use of the apparatus and does not materially limit the claim.

Another difference between the proposed Count 3 and the claim 54 of the '631 Patent is that the Count recites

means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two points

whereas claim 54 of the '631 Patent recites

wherein said circuitry for generating a non-excitatory electric field generates a field of a magnitude, shape, duty cycle, phase, frequency and duration suitable to reduce the output flow, contractility, or pressure of said chamber, when surgery is performed on tissue perfused by the flow of said chamber, and wherein said field is unable to generate a propagating action potential, and thereafter performing the required surgical procedure on said area.

The results of “said field is unable to generate a propagating action potential” and “non-excitatory electric potential” have the same meaning and are simply expressed in a different form of words. The sets of parameters controlled in each case are so thoroughly overlapping as to patentably indistinct from one another. The wording as to “reduce the output flow, contractility, or pressure of said chamber, when surgery is performed on tissue perfused by the flow” is simply a statement of intended use of the apparatus and does not materially limit the claim.

E.2. Correspondence of Application Claims to Proposed Count 3

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 15 of this application correspond to proposed Count 3. This correspondence is explained as follows.

Independent claim 15 of the present application corresponds closely to proposed Count 3 and merely uses the intended use phrase “for varying conduction velocity of a muscle” instead of “contraction force” in the preamble.

E.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

E.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant’s claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

F. Proposed Count 4 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 4 directed to a method for creating a non-excitatory electric potential between points located in the vicinity of a muscle:

COUNT 4

A method for varying a contraction force of a muscle, comprising
creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and
controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.

F.1. Correspondence of Patent Claims to Proposed Count 4

F.1.a The '484 Patent and Proposed Count 4

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 7 of the '484 Patent correspond to proposed Count 3. This correspondence is explained as follows.

Independent claims 7, 15, 19, 22, 23, and 25 of the '484 Patent correspond to proposed Count 4, although they are not exact duplicates thereof.

The only difference between claim 7 and proposed Count 4 is that claim 7 recites "reducing the contraction force of a muscle" in its preamble instead of "varying." One difference between claim 15 and proposed Count 4 is that claim 15 recites "reducing the contraction force of a treated area of the cardiac muscle" and "to obtain the desired reduction in muscle contraction at the treated heart area" whereas proposed Count 4 uses "varying" and "variation." Reduction is a subset of variation, and thus obvious. One difference between claim 19 and proposed Count 4 is that claim 19 recites that the "electric potential being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction at the affected heart area." One difference between claim 23 and proposed Count 4 is that claim 23 recites "reducing the contraction force of the heart muscle" and the "electric potential being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction." One difference between claim 25 and proposed Count 4 is that claim 25 recites "reducing the contraction force of the area of the

cardiac muscle” and “to obtain the desired reduction in muscle contraction at the heart area.”

The difference between claim 22 and proposed Count 4 is that claim 22 recites “selectively and reversibly reducing the oxygen consumption of an area of a muscle” and the “electric potential being of an intensity and polarity suitable to obtain the desired reduction in oxygen consumption at the affected heart area.”

Another difference between claim 15 and proposed Count 4 is that claim 15 recites “for performing heart surgery” and the step of “thereafter performing surgery thereon.” It is noted that only a cursory recitation is made to any surgery in the method and that the claim is really directed to a method of *preparing* to perform surgery. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

Another difference between claim 19 and proposed Count 4 is that claim 19 recites “promoting the healing of the cardiac muscle after myocardial infarct.” The promotion of cardiac muscle healing is simply an inherent result of the recited method steps and, thus, is not a patentably distinct limitation.

Another difference between claim 23 and proposed Count 4 is that claim 23 recites “for treating congenital or acquired hypertrophic cardiomyopathy” in the preamble. Any utility this method may have in treatment of hypertrophic cardiomyopathy is simply an inherent result of the recited method steps and, thus, is not a patentably distinct limitation.

Another difference between claim 25 and proposed Count 4 is that claim 25 recites “for performing cardiac ablation” in the preamble and the step of “thereafter performing the ablation thereon.” It is noted that only a cursory recitation is made to any ablation in the method and that the claim is really directed to a method of *preparing* to perform cardiac ablation. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

Dependent claims 6, 9/7, 17/15, 18/15, 32/19, 32/22, and 32/23 of the ‘484 Patent also correspond to proposed Count 4. That is because these dependent claims describe in greater detail various aspects of the same invention to which proposed Count 4 is directed.

F.1.b The ‘476 Patent and Proposed Count 4

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 23 of the ‘476 Patent corresponds to proposed Count 4. This correspondence is explained as follows.

Independent claim 23 of the ‘476 Patent corresponds to proposed Count 4, although it is

not an exact duplicate thereof.

One difference between claim 23 of the '476 Patent and proposed Count 4 is that the proposed Count recites broadly a method, whereas the claim recites specifically that the method is for "treating an abnormal activation of the heart, particularly fibrillation." The treatment of the heart, particularly one that happens to be in fibrillation, is simply an inherent result of the recited method steps and, thus, is not a patentably distinct limitation.

Another difference claim 23 of the '476 Patent and proposed Count 4 is that the claim recites specifically that electric potential (or equivalently, "field") is applied to the "Right Ventricle," whereas the proposed Count recites application of such "between at least two points located in the vicinity of the muscle." The choice of which specific muscle region to stimulate is well within the level of ordinary skill in the surgical art and, thus, is not a patentably distinct limitation.

Another difference between claim 23 of the '476 Patent and proposed Count is that the claim recites:

of a magnitude, shape and duration suitable to treat the abnormal
activation condition, wherein said field is unable to generate a propagating
action potential

whereas the proposed Count recites:

controlling one or more of the parameters consisting of start time,
duration, magnitude and polarity of the non-excitatory electric potential
created between said at least two points.

The results of "said field is unable to generate a propagating action potential" and "non-excitatory electric potential" have the same meaning and are simply expressed in a different form of words. The sets of parameters controlled in each case are so thoroughly overlapping as to be patentably indistinct from one another.

F.1.c The '631 Patent and Proposed Count 4

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 27 of the '631 Patent corresponds to proposed Count 4. This correspondence is explained as follows.

Independent claim 27 of the '631 Patent corresponds to proposed Count 4, although it is not an exact duplicate thereof.

One difference between claim 27 of the '631 Patent and proposed Count 4 is that the proposed Count recites broadly a method, whereas the claim recites specifically that the method is for "treating an abnormal activation of the heart, particularly fibrillation." The treatment of the heart, particularly one that happens to be in fibrillation, is simply an inherent result of the recited method steps and, thus, is not a patentably distinct limitation.

Another difference claim 27 of the '631 Patent and proposed Count 4 is that the claim recites specifically that electric potential (or equivalently, "field") is applied to the "heart," whereas the proposed Count recites application of such "between at least two points located in the vicinity of the muscle." The choice of which specific muscle region to stimulate is well within the level of ordinary skill in the surgical art and, thus, is not a patentably distinct limitation.

Another difference between claim 27 of the '631 Patent and proposed Count 4 is that the claim recites:

of a magnitude, shape and duration suitable to treat the abnormal activation condition, wherein said field is unable to generate a propagating action potential

whereas the proposed Count recites:

controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.

The results of "said field is unable to generate a propagating action potential" and "non-excitatory electric potential" have the same meaning and are simply expressed in a different form of words. The sets of parameters controlled in each case are so thoroughly overlapping as to patentably indistinct from one another.

F.2. Correspondence of Application Claims to Proposed Count 4

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 17, 19/17, 24, and 34 of this application correspond to proposed Count 4. This correspondence is explained as follows.

Independent claims 17, 24, and 34 of the present application correspond to proposed Count 4 although they are not exact duplicates thereof.

The only difference between claim 17 and proposed Count 4 is that claim 17 recites

“varying the conduction velocity” instead of “contraction force of a muscle” in its preamble. One difference between claim 24 and proposed Count 4 is that claim 24 recites “varying the conduction velocity” instead of “contraction force of a treated area of the cardiac muscle” and “to obtain the desired variation in conduction velocity” instead of “muscle contraction at the treated heart area.” One difference between claim 34 and proposed Count 4 is that claim 34 recites “varying the conduction velocity” instead of “contraction force of a treated area of the cardiac muscle” and “to obtain the desired variation in conduction velocity” instead of “muscle contraction at the treated heart area.”

Another difference between claim 24 and proposed Count 4 is that claim 24 recites “for performing heart treatment” and the step of “thereafter performing treatment thereon.” Another difference between claim 34 and proposed Count 4 is that claim 34 recites “for performing cardiac treatment” in the preamble and the step of “thereafter performing the treatment thereon.”

It is noted that only a cursory recitation is made to any treatment in the claimed method and that these claims are really directed to a method of *preparing* to perform cardiac treatment. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

Dependent claim 19/17 of the present application also correspond to proposed Count 4. That is because this dependent claim describes in greater detail various aspects of the same invention to which proposed Count 4 is directed.

F.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

F.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant’s claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

G. Proposed Count 5 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 5 directed to a method that causes a non-excitatory electric current to flow between points located in the vicinity of a muscle:

COUNT 5

A method for varying the contraction force of a muscle, comprising causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.

G.1. **Correspondence of Patent Claims to Proposed Count 5**

In accordance with 37 C.F.R. § 1.607(a)(3), Applicant identifies that claims 8, 9/8, 10-12, 16, 17/16, 18/16, 20, 21, 24, 26-29, 32/16, 32/20, 32/21, and 32/24 of the '484 Patent correspond to proposed Count 5. This correspondence is explained as follows.

Independent claims 8, 16, 20, 21, 24, and 26 of the '484 Patent correspond to proposed Count 5 although they are not exact duplicates thereof.

The only difference between claim 8 and proposed Count 5 is that claim 8 recites “for reducing the contraction force of a muscle” in the preamble whereas Count 5 is for “varying the contraction force.” One difference between claim 16 and proposed Count 5 is that claim 16 recites “reducing the contraction force of a treated area of the cardiac muscle” and to “obtain the desired reduction in muscle contraction at the treated heart area.” One difference between claim 20 and proposed Count 5 is the recitation of the “electric current being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction at the affected heart area.” One difference between claim 24 and proposed Count 5 is that claim 24 recites “reducing the contraction force of the heart muscle” and the “electric current being of an intensity and polarity suitable to obtain the desired reduction in muscle contraction.” One difference between claim 26 and proposed Count 5 is that claim 26 recites “reducing the contraction force of the area of the cardiac muscle” and “thereby to obtain the desired reduction in muscle contraction at the heart area.”

The only difference between claim 21 and proposed Count 5 is the recitation of “for

selectively and reversibly reducing the oxygen consumption of an area of a muscle” in the preamble, and of the “electric current being of an intensity and polarity suitable to obtain the desired reduction in oxygen consumption at the affected heart area.”

Another difference between claim 16 and proposed Count 5 is that claim 16 recites “for performing heart surgery” and the step of “thereafter performing surgery thereon.” It is noted that only a cursory recitation is made to any surgery in the method and that the claim is really directed to a method of *preparing* to perform surgery. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

Another difference between claim 20 and proposed Count 5 is that claim 20 recites “promoting the healing of the cardiac muscle after myocardial infarct.” The promotion of cardiac muscle healing is simply an inherent result of the recited method steps and, thus, is not a patentably distinct limitation.

Another difference between claim 24 and proposed Count 5 is that claim 24 recites “for treating congenital or acquired hypertrophic cardiomyopathy” in the preamble. Any utility this method may have in treatment of hypertrophic cardiomyopathy is simply an inherent result of the recited method steps and, thus, is not a patentably distinct limitation.

Another difference between claim 26 and proposed Count 5 is that claim 26 recites “for performing cardiac ablation” in the preamble and the step of “thereafter performing the ablation thereon.” It is noted that only a cursory recitation is made to any ablation in the method and that the claim is really directed to a method of *preparing* to perform cardiac ablation. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

The correspondence of independent claims 8, 16, 20, 21, 24, and 26 of the ‘484 Patent to proposed Count 5 is set out in tabular form in Attachment I.

Dependent claims 9/8, 10-12, 17/16, 18/16, 27-29, 32/16, 32/20, 32/21, and 32/24 of the ‘484 Patent also correspond to proposed Count 5. That is because these dependent claims describe in greater detail various aspects of the same invention to which proposed Count 5 is directed.

G.2. Correspondence of Application Claims to Proposed Count 5

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 18, 19/18, 20, 22, 25, 35, 36, and 38 of this application correspond to proposed Count 5. This correspondence is explained as follows.

Independent claims 18, 25, and 35 of the present application correspond to proposed Count 5 although they are not exact duplicates thereof.

The only difference between claim 18 and proposed Count 5 is that claim 18 recites “for varying conduction velocity of a muscle” in the preamble instead of “varying the contraction force.” One difference between claim 25 and proposed Count 5 is that claim 25 recites “varying conduction velocity of a treated area of the cardiac muscle” and to “obtain the desired variation in conduction velocity.” One difference between claim 35 and proposed Count 5 is that claim 35 recites “varying the conduction velocity of the area of the cardiac muscle” and “thereby to obtain the desired variation in conduction velocity at the heart area.” As illustrated in figure 6 and 7, varying the conduction velocity can be done based on timing. The conduction velocity inherently affects the contraction force, thus varying (and inherently including reducing) contraction force.

Another difference between claim 25 and proposed Count 5 is that claim 25 recites “for performing heart treatment” and the step of “thereafter performing treatment thereon.” It is noted that only a cursory recitation is made to any heart treatment in the method and that the claim is really directed to a method of *preparing* to perform heart treatment. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

Another difference between claim 35 and proposed Count 5 is that claim 35 recites “for performing cardiac treatment” in the preamble and the step of “thereafter performing the treatment thereon.” It is noted that only a cursory recitation is made to any cardiac treatment in the method and that the claim is really directed to a method of *preparing* to perform cardiac treatment. That is simply an intended purpose of the method and does not amount to a patentably distinct limitation.

Dependent claims 19/18, 20-22, 36, and 38 of the present application also correspond to proposed Count 5. That is because these dependent claims describe in greater detail various aspects of the same invention to which proposed Count 5 is directed.

G.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference

in accordance with 37 CFR 41.202(a)(3).

G.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant's claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

H. Proposed Count 6 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 6 directed to creating a non-excitatory electric potential between points located in the vicinity of a muscle:

COUNT 6

A method for varying contraction force of a muscle, comprising

causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and

controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points,

wherein the non-excitatory electric current is a DC current; and

wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.

H.1. Correspondence of Patent Claims to Proposed Count 8

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 12 of the '484 Patent correspond to proposed Count 6. This correspondence is explained as follows.

Dependent claim 12 of the '484 Patent corresponds closely to proposed Count 6, with "reducing" in the preamble instead of "varying." Reducing is an obvious subset of varying. Note that for "DC current" in claim 12 to have proper antecedent basis, it inherently must depend on claim 10 and not claim 8.

H.2. Correspondence of Application Claims to Proposed Count 6

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 22 of this application correspond to proposed Count 6. This correspondence is explained as follows.

Dependent claim 22 of the present application corresponds closely to proposed Count 6, with the preamble reciting variation of “conduction velocity” instead of “muscle contraction.” Conduction velocity is intimately linked with contraction force of a muscle.

H.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

H.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant’s claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

I. Proposed Count 7 for Interference

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant proposes the following Count 7 directed to creating a non-excitatory electric potential between points located in the vicinity of a muscle:

COUNT 7

A method for varying contraction force of a muscle, comprising

causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and

controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points,

wherein the non-excitatory electric current is a DC current;

wherein the flow of the non-excitatory DC electric current is synchronized to heart activity; and

wherein the non-excitatory DC electric current flows not at every beat of the heart.

I.1. Correspondence of Patent Claims to Proposed Count 7

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 13 of the '484 Patent correspond to proposed Count 6. This correspondence is explained as follows.

Dependent claim 13 of the '484 Patent corresponds closely to proposed Count 6, with "reducing" in the preamble instead of "varying." Reducing is an obvious subset of varying.

I.2. Correspondence of Application Claims to Proposed Count 7

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claim 22 of this application correspond to proposed Count 6. This correspondence is explained as follows.

Dependent claim 22 of the present application corresponds closely to proposed Count 6, with the preamble reciting variation of "conduction velocity" instead of "muscle contraction." Conduction velocity is intimately linked with contraction force of a muscle. Further, the non-excitatory current is part of "a first phase of a bi-phasic stimulation pulse." The use of demand pacing, wherein pacing pulses are only supplied as needed (not at every beat of the heart) renders this limitation obvious, so as to obviously meet the limitations of proposed Count 7.

I.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

I.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant's claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

J. Proposed Count 8 for Interference

In accordance with 37 C.F.R. § 1.607(a)(2), Applicant proposes the following Count 8 directed to creating a non-excitatory electric potential between points located in the vicinity of a muscle:

COUNT 8

A method for reducing the contraction force of a muscle, comprising:
providing means for creating an electric potential between at least two points located
in the vicinity of the muscle;
providing means for causing a non-excitatory DC electric current to flow between
said at least two point;
providing means for switching the current polarity between said at least two points;
and
providing means for controlling the start time, duration and magnitude of the electric
current flowing between said at least two points.

J.1. Correspondence of Patent Claims to Proposed Count 8

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 40-43 of the '484 Patent correspond to proposed Count 6. This correspondence is explained as follows.

Independent claim 40 of the '484 Patent corresponds closely to proposed Count 6, with "reducing" in the preamble instead of "varying." Reducing is an obvious subset of varying.

Dependent claims 41-43 of the '484 Patent also correspond to proposed Count 6. That is because these dependent claims describe in greater detail various aspects of the same invention to which proposed Count 6 is directed.

J.2. Correspondence of Application Claims to Proposed Count 8

In accordance with 37 C.F.R. § 41.202(a)(2), Applicant identifies that claims 47-50 of this application correspond to proposed Count 6. This correspondence is explained as follows.

Independent claim 47 of the present application corresponds closely to proposed Count 6, with the preamble reciting variation of "conduction velocity" instead of "muscle contraction." Conduction velocity is intimately linked with contraction force of a muscle.

Dependent claims 50 of the present application also corresponds to proposed Count 6. That is because this dependent claim describe in greater detail various aspects of the same invention to which proposed Count 6 is directed.

J.3. Comparison to Show Interference in Accordance with 37 CFR 41.202(a)(3)

The attached charts of Appendix A include the required comparison to show Interference in accordance with 37 CFR 41.202(a)(3).

J.4. Applicant will Prevail on Priority

Applicant will prevail on priority under 37 C.F.R. 41.202(a)(4) since Applicant's claims can claim an earlier priority date of August 19, 1996 (as explained in the attached chart under 37 CFR 41.202(a)(5) which finds support in the disclosure of U.S. Patent 5,871,506 that has priority to August 19, 1996), whereas the earliest possible priority date that can be claimed in the patents is September 16, 1996.

K. Application Of The Terms Of Application Claims To The Disclosure Of The Application

In accordance with 37 C.F.R. § 41.202(a)(5), Applicant applies the terms of the new application claims to Applicant's own disclosure. Please refer to Attachment B, which sets out in detail how the Applicant's disclosure supports each and every limitation of pending claims.

L. Conclusion

For the above reasons, Applicant respectfully submits that it is appropriate for the Examiner to declare an interference between the present application and U.S. Patent Nos. 6,233,484, 6,330,476, and 6,317,631. Early notice of such is respectfully requested.

Respectfully submitted,

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ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 1</u>	<u>Applicant's CLAIM 12</u>	<u>'484 CLAIM 1</u>
<p>Apparatus comprising circuitry</p> <p>for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>comprising circuitry for controlling the start time and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity,</p> <p>said circuitry not operating at every beat of the heart.</p>	<p>Apparatus comprising circuitry</p> <p>for creating a non-excitatory electric potential between at least two points located in the vicinity of a muscle,</p> <p>comprising circuitry for controlling the start time and/or the duration of the electric potential generated between said at least two points which is synchronized to heart activity,</p> <p>said non-excitatory electric potential being a first phase of a biphasic pacing pulse.</p>	<p>Apparatus comprising circuitry</p> <p>for creating a non-excitatory electric potential between at least two points located in the vicinity of a muscle,</p> <p>comprising circuitry for controlling the start time and/or the duration of the electric potential generated between said at least two points which is synchronized to heart activity,</p> <p>said circuitry not operating at every beat of the heart.</p>

ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 2</u>	<u>Applicant's CLAIM 13</u>	<u>'484 CLAIM 2</u>
<p>Implantable apparatus comprising</p> <p>circuitry for causing a non-excitatory electric current to flow between at least two points located in the vicinity of a muscle and</p> <p>circuitry for controlling the start time and/or duration of the electric current,</p> <p>wherein said circuitry for controlling does not operate at every beat of the heart.</p>	<p>Implantable apparatus comprising</p> <p>circuitry for causing a non-excitatory electric current to flow between at least two points located in the vicinity of a muscle and</p> <p>circuitry for controlling the start time and/or duration of the electric current,</p> <p>wherein said non-excitatory electric current is a first phase of a bi-phasic pacing pulse.</p>	<p>Implantable apparatus comprising</p> <p>circuitry for causing a non-excitatory electric current to flow between at least two points located in the vicinity of a muscle and</p> <p>circuitry for controlling the start time and/or duration of the electric current,</p> <p>wherein said circuitry for controlling does not operate at every beat of the heart.</p>

ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 3</u>	<u>Applicant's CLAIM 15</u>	<u>'484 CLAIM 5</u>
<p>Apparatus, comprising:</p> <p>means for creating an electric potential between at least two points located in the vicinity of the muscle;</p> <p>means for causing a non-excitatory DC electric current to flow between said at least two point, if desired; and</p> <p>means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two points.</p>	<p>Apparatus for varying conduction velocity of a muscle, comprising:</p> <p>means for creating an electric potential between at least two points located in the vicinity of the muscle;</p> <p>means for causing a non-excitatory DC electric current to flow between said at least two points, if desired; and</p> <p>means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two points.</p>	<p>Apparatus for reducing the contraction force of a muscle, comprising:</p> <p>means for creating an electric potential between at least two points located in the vicinity of the muscle;</p> <p>means for causing a non-excitatory DC electric current to flow between said at least two point, if desired; and</p> <p>means for controlling the start time, duration and magnitude of the non-excitatory electric potential and/or of the non-excitatory electric current flowing between said at least two points.</p>

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INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 4</u>	<u>Applicant's CLAIM 17</u>	<u>'484 CLAIM 7</u>
<p>A method for varying a contraction force of a muscle,</p> <p>comprising creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.</p>	<p>A method for varying conduction velocity of a muscle,</p> <p>comprising creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.</p>	<p>A method for reducing the contraction force of a muscle,</p> <p>comprising creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.</p>

ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 5</u>	<u>Applicant's CLAIM 18</u>	<u>'484 CLAIM 8</u>
<p>A method for varying the contraction force of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.</p>	<p>A method for varying conduction velocity of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle as a first phase of a bi-phasic stimulation pulse, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.</p>	<p>A method for reducing the contraction force of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.</p>

ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 6</u>	<u>Applicant's CLAIM 22</u>	<u>'484 CLAIM 12</u>
<p>A method for varying contraction force of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points,</p> <p>wherein the non-excitatory electric current is a DC current; and</p> <p>wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.</p>	<p>A method for varying conduction velocity of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle as a first phase of a bi-phasic stimulation pulse, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points;</p> <p>wherein the non-excitatory electric current is a DC current; and</p> <p>wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.</p>	<p>A method for reducing the contraction force of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points;</p> <p>wherein the non-excitatory electric current is a DC current; and</p> <p>wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.</p>

ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 7</u>	<u>Applicant's CLAIM 22</u>	<u>'484 CLAIM 13</u>
<p>A method for varying contraction force of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points,</p> <p>wherein the non-excitatory electric current is a DC current;</p> <p>wherein the flow of the non-excitatory DC electric current is synchronized to heart activity; and</p> <p>wherein the non-excitatory DC electric current flows not at every beat of the heart.</p>	<p>A method for varying conduction velocity of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle as a first phase of a bi-phasic stimulation pulse, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points;</p> <p>wherein the non-excitatory electric current is a DC current; and</p> <p>wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.</p>	<p>A method for reducing the contraction force of a muscle, comprising</p> <p>causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points;</p> <p>wherein the non-excitatory electric current is a DC current;</p> <p>wherein the flow of the non-excitatory DC electric current is synchronized to heart activity; and</p> <p>wherein the non-excitatory DC electric current flows not at every beat of the heart.</p>

ATTACHMENT A

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(3)

<u>COUNT 8</u>	<u>Applicant's CLAIM 47</u>	<u>'484 CLAIM 40</u>
<p>A method for varying the contraction force of a muscle, comprising:</p> <p>providing means for creating an electric potential between at least two points located in the vicinity of the muscle;</p> <p>providing means for causing a non-excitatory DC electric current to flow between said at least two point;</p> <p>providing means for switching the current polarity between said at least two points; and</p> <p>providing means for controlling the start time, duration and magnitude of the electric current flowing between said at least two points.</p>	<p>A method for varying conduction velocity of a muscle, comprising:</p> <p>providing means for creating an electric potential between at least two points located in the vicinity of the muscle;</p> <p>providing means for causing a non-excitatory DC electric current to flow between said at least two point;</p> <p>providing means for switching the current polarity between said at least two points; and</p> <p>providing means for controlling the start time, duration and magnitude of the electric current flowing between said at least two points.</p>	<p>A method for reducing the contraction force of a muscle, comprising:</p> <p>providing means for creating an electric potential between at least two points located in the vicinity of the muscle;</p> <p>providing means for causing a non-excitatory DC electric current to flow between said at least two point;</p> <p>providing means for switching the current polarity between said at least two points; and</p> <p>providing means for controlling the start time, duration and magnitude of the electric current flowing between said at least two points.</p>



ATTACHMENT B

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(5)

<u>CLAIM 12</u>	<u>SUPPORT IN SPECIFICATION</u>
Apparatus comprising circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of a muscle, comprising circuitry for controlling the start time and/or the duration of the electric potential generated between said at least two points which is synchronized to heart activity, said non-excitatory electric potential being a first phase of a bi-phasic pacing pulse.	<p>“Pacemaker electronics needed to practice the method of the present invention are well known to those skilled in the art. Current pacemaker electronics are capable of being programmed to deliver a variety of pulses, including those disclosed herein.” Col. 4:22-26;</p> <p>“the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16; Electrical “current,” mentioned in col. 1:34, 38, 67, etc., inherently requires an electric potential between two locations in order to flow.</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; “the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12;</p> <p>“The anodal stimulation component of biphasic electrical stimulation augments cardiac contractility by hyperpolarizing the tissue prior to excitation,” col. 7:62-65.</p>

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ATTACHMENT B

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(5)

<u>CLAIM 13</u>	<u>SUPPORT IN SPECIFICATION</u>
Implantable apparatus comprising circuitry	“Pacemaker electronics needed to practice the method of the present invention are well known to those skilled in the art. Current pacemaker electronics are capable of being programmed to deliver a variety of pulses, including those disclosed herein.” Col. 4:22-26;
for causing a non-excitatory electric current to flow between at least two points located in the vicinity of a muscle and circuitry for controlling the start time and/or duration of the electric current,	“the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16; “each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; Electrical “current,” mentioned in col. 1:34, 38, 67, etc.
wherein said non-excitatory electric current is a first phase of a bi-phasic pacing pulse.	“The anodal stimulation component of biphasic electrical stimulation augments cardiac contractility by hyperpolarizing the tissue prior to excitation,” col. 7:62-65.

ATTACHMENT B

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(5)

<u>CLAIM 14</u>	<u>SUPPORT IN SPECIFICATION</u>
Apparatus	“Pacemaker electronics needed to practice the method of the present invention are well known to those skilled in the art. Current pacemaker electronics are capable of being programmed to deliver a variety of pulses, including those disclosed herein.” Col. 4:22-26;
for varying conduction velocity of a muscle,	See variation of conduction velocity illustrated in figure 6;
comprising circuitry for creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle,	Electrical “current,” mentioned in col. 1:34, 38, 67, etc., inherently requires an electric potential between two locations in order to flow; “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;
and comprising circuitry for controlling the start time and/or duration of the electric current flowing between said at least two points which is synchronized to heart activity,	“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; “the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12;
said non-excitatory electric potential being a first phase of a bi-phasic pacing pulse.	“The anodal stimulation component of biphasic electrical stimulation augments cardiac contractility by hyperpolarizing the tissue prior to excitation,” col. 7:62-65.

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(5)

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ATTACHMENT B

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(5)

<u>CLAIM 17</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for varying conduction velocity of a muscle,</p> <p>comprising creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points.</p>	<p>See variation of conduction velocity illustrated in figure 6;</p> <p>Electrical “current,” mentioned in col. 1:34, 38, 67, etc., inherently requires an electric potential between two locations in order to flow; “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; “the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12;</p>

<u>CLAIM 18</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for varying conduction velocity of a muscle,</p> <p>comprising causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle</p> <p>as a first phase of a bi-phasic stimulation pulse, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points.</p>	<p>See variation of conduction velocity illustrated in figure 6;</p> <p>Electrical “current,” mentioned in col. 1:34, 38, 67, etc., “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“The anodal stimulation component of biphasic electrical stimulation augments cardiac contractility by hyperpolarizing the tissue prior to excitation,” col. 7:62-65.</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; “the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12;</p>

ATTACHMENT B

INTERFERENCE CHART UNDER 37 C.F.R. 41.202(a)(5)

<u>CLAIM 19</u>	<u>SUPPORT IN SPECIFICATION</u>
A method according to claim 17 or 18, wherein the muscle is a cardiac muscle.	“In this fashion, pulse conduction through the cardiac muscle is improved...” Abstract

<u>CLAIM 20</u>	<u>SUPPORT IN SPECIFICATION</u>
A method according to claim 18, wherein the non-excitatory electric current is a DC current.	“Current flow” from a “small battery powered electrical stimulator” is inherently direct current (“DC”).

<u>CLAIM 22</u>	<u>SUPPORT IN SPECIFICATION</u>
A method according to claim 18, wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.	“the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12

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<u>CLAIM 24</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for performing heart treatment, comprising</p> <p>varying conduction velocity of a treated area of the cardiac muscle, by creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points, thereby to obtain the desired variation in conduction velocity at the treated heart area and thereafter performing treatment thereon.</p>	<p>“a patient suffering from a conduction disorder can be helped by an artificial pacemaker,” col. 1:53-54;</p> <p>FIG. 6 graphs conduction velocity transverse to the fiber vs pacing duration resulting from leading anodal biphasic pulse; Electrical “current,” mentioned in col. 1:34, 38, 67, etc., inherently requires an electric potential between two locations in order to flow; “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; “the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12;</p>

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<u>CLAIM 25</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for performing heart treatment, comprising</p> <p>varying conduction velocity of a treated area of the cardiac muscle, by causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points, thereby to obtain the desired variation in conduction velocity at the treated heart area and thereafter performing treatment thereon.</p>	<p>“a patient suffering from a conduction disorder can be helped by an artificial pacemaker,” col. 1:53-54;</p> <p>FIG. 6 graphs conduction velocity transverse to the fiber vs pacing duration resulting from leading anodal biphasic pulse; Electrical “current,” mentioned in col. 1:34, 38, 67, etc., “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4.</p>

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<u>CLAIM 34</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for performing cardiac treatment, comprising</p> <p>varying conduction velocity of the area of the cardiac muscle to be treated, by creating a non-excitatory electric potential between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric potential created between said at least two points, thereby to obtain the desired variation in conduction velocity at the heart area to be treated, and thereafter performing the treatment thereon.</p>	<p>“a patient suffering from a conduction disorder can be helped by an artificial pacemaker,” col. 1:53-54;</p> <p>FIG. 6 graphs conduction velocity transverse to the fiber vs pacing duration resulting from leading anodal biphasic pulse; Electrical “current,” mentioned in col. 1:34, 38, 67, etc., inherently requires an electric potential between two locations in order to flow; “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4.</p>

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<u>CLAIM 35</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for performing cardiac treatment, comprising</p> <p>varying conduction velocity of the area of the cardiac muscle to be treated, by causing a non-excitatory electric current to flow between at least two points located in the vicinity of the muscle, and</p> <p>controlling one or more of the parameters consisting of start time, duration, magnitude and polarity of the non-excitatory electric current flowing between said at least two points, thereby to obtain the desired variation in conduction velocity at the heart area to be treated, and thereafter performing the treatment thereon.</p>	<p>“a patient suffering from a conduction disorder can be helped by an artificial pacemaker,” col. 1:53-54;</p> <p>FIG. 6 graphs conduction velocity transverse to the fiber vs pacing duration resulting from leading anodal biphasic pulse; Electrical “current,” mentioned in col. 1:34, 38, 67, etc., “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4.</p>

<u>CLAIM 36</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method according to any one of claims 25 or 35, wherein the non-excitatory electric current is a DC current.</p>	<p>“Current flow” from a “small battery powered electrical stimulator” is inherently direct current (“DC”).</p>

<u>CLAIM 38</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method according to any one of claims 25 or 35, wherein the flow of the non-excitatory DC electric current is synchronized to heart activity.</p>	<p>“the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12</p>

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<u>CLAIM 47</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method for varying conduction velocity of a muscle, comprising:</p> <p>providing means for creating an electric potential between at least two points located in the vicinity of the muscle; providing means for causing a non-excitatory DC electric current to flow between said at least two point;</p> <p>providing means for switching the current polarity between said at least two points; and providing means for controlling the start time, duration and magnitude of the electric current flowing between said at least two points.</p>	<p>FIG. 6 graphs conduction velocity transverse to the fiber vs pacing duration resulting from leading anodal biphasic pulse;</p> <p>Electrical “current,” mentioned in col. 1:34, 38, 67, etc., inherently requires an electric potential between two locations in order to flow; “Current flow” from a “small battery powered electrical stimulator” is inherently direct current (“DC”), “the first phase of stimulation is an anodal pulse at maximum subthreshold amplitude for a long duration,” col. 4:14-16;</p> <p>“each stimulation phase having a polarity, amplitude, shape and duration,” col. 4:2-4; “the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12.</p>

<u>CLAIM 50</u>	<u>SUPPORT IN SPECIFICATION</u>
<p>A method according to claim 47 or 48, wherein the means for causing a non-excitatory DC electric current to flow, are synchronized to heart activity.</p>	<p>“the first phase is administered over 200 milliseconds post heart beat,” col. 4:11-12.</p>